UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CAROL LEWIS,

Plaintiff,

v. Case 1:15-cv-13530-NMG

SYLVIA BURWELL,
Secretary of the U.S. Department of Health
and Social Services,

Defendant.

MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGEMENT

I. INTRODUCTION

The issue before this Court is narrow: Is the final decision of Defendant, the Secretary ("the Secretary") of the Department of Health and Human Services ("HHS"), refusing to cover claims for a continuous glucose monitor ("CGM") and related supplies provided to Ms. Carol Lewis, a Medicare beneficiary, arbitrary and capricious, not supported by substantial evidence,[1] and contrary to law?

The answer is clear – Medicare coverage is supported by the facts and law. Continuous glucose monitoring is recognized nationally as the medical standard of care for individuals suffering from Type 1 diabetes with hypoglycemic unawareness and is consistent with the Secretary's coverage policies and other determinations. Plaintiff Carol Lewis seeks an order

[1] The Secretary's denial must be supported by evidence in the Administrative Record ("AR") which Appellant cites using the convention "AR".

from this Court finding that the Secretary's denial is not supported by substantial evidence and is arbitrary and capricious, and ordering coverage of Ms. Lewis' CGM and related supplies.

II. STATUTORY AND REGULATORY BACKGROUND

A. General Background of the Medicare Program

The Medicare Act establishes a program of health insurance for the aged, disabled, and individuals with end-stage renal disease. 42 U.S.C. §§1395-1395ccc. Medicare includes Parts A through D. This action arises under Part B, which generally covers non-institutional claims including claims for durable medical equipment ("DME"). The Secretary, the Federal official responsible for administering the Medicare program, has delegated that responsibility to the Centers for Medicare & Medicaid Services ("CMS"), an agency within HHS. CMS has contracted out many Medicare administrative functions, including some Medicare coverage determinations to private organizations. *See, e.g.*, 42 U.S.C. §1395h. The four Durable Medical Equipment Administrative Contractors ("DMACs"), are contractors who, among other things, process claims and set policy for durable medical equipment.

B. The Statutory and Regulatory Definition of DME

DME is a benefit provided by Medicare Part B. Per the Social Security Act ("SSA"):

> The term "durable medical equipment" includes iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient's home . . . whether furnished on a rental basis or purchased, and includes blood testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin.[2]

CMS has interpreted the statutory definition and has established criteria for an item to be designated DME which includes the following:

> Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:

[2] SSA §1861 (n).

(1) Can withstand repeated use;
(2) Is primarily and customarily used to serve a medical purpose;
(3) Generally is not useful to an individual in the absence of an illness or injury; and
(4) Is appropriate for use in the home.[3]

DME must also be "necessary and reasonable for the treatment of the patient's illness or injury to improve the functioning of his or her malformed body member." Medicare regulations state that "[i]n most instances, no development will be needed to determine whether a specific item of equipment is medical in nature," but if such ambiguity exists, "this development would include the advice of local medical organizations . . . and specialists in the field of physical medicine and rehabilitation."[4] "[P]recautionary-type equipment (such as preset portable oxygen units) . . . are considered nonmedical in nature."[5]

CMS issued a National Coverage Determination ("NCD") relating to DME, NCD 280.1. An NCD is "a determination by the Secretary that a particular item or service is covered nationally under Medicare." 42 C.F.R. §405.1060(a)(1). An NCD is binding on all Medicare administrative contractors ("MACs"), administrative law judges ("ALJs") and the Medicare Appeals Council ("Council"). 42 C.F.R. §405.1060(a)(4). NCD 280.1 reiterates the four requirements for an item to be DME. NCD 280.1 includes exemplars of items considered to be DME, and indicates that if an item does not appear among the generic categories listed, the DMACs should consider whether an item is covered under Medicare's DME benefit based on the advice of medical consultants by taking into account: (1) whether the item has been approved by the United States Food and Drug Administration ("FDA") and is otherwise generally considered safe and effective and (2) whether it is reasonable and necessary for the patient. NCD 280.1

[3] 42 C.F.R. §414.202.
[4] Medicare Benefit Policy Manual ("MBPM"), Ch. 15, §110.1.B.
[5] Id. at §110.1.B.2

indicates blood glucose monitors are considered to be DME provided the Medicare beneficiary (not a specific device) satisfies the conditions listed in NCD 40.2.

Medicare has covered glucose monitors under NCD 40.2 since at least 1995. NCD 40.2 states glucose monitors are covered if (1) the patient has a diagnosis of diabetes; (2) the patient can use the prescribed device; and (3) the device is designed for home use.

C. Local Coverage Determinations and Articles

Where CMS has established a national coverage policy, a Medicare contractor may, but is not required to, establish a local coverage determination ("LCD") that applies to the claims processed by that contractor. An LCD may not conflict with an NCD. LCDs are based on the peer-reviewed literature and general acceptance by the medical community. See Medicare Program Integrity Manual ("MPIM"), Ch. 13, §13.7.1. LCDs are developed in consultation with the relevant medical community. MPIM, Ch. 13, §§13.7 and 13.8. An LCD that is contrary to the standard of care must be based on sufficient evidence to convincingly refute evidence presented in support of coverage. MPIM, Ch. 13, §13.8.

Consistent with NCDs 40.2 and 280.1, the relevant DMAC, National Heritage Insurance Corp. ("NHIC") issued an LCD indicating the coverage criteria for blood glucose monitors and related supplies.[6] The LCD does not indicate CGMs are not a covered service. The LCD included the billing codes for the components and supplies of a CGM system. LCDs are not binding on an ALJ or the Council although they are entitled to deference. 42 C.F.R. §405.1062(a). An ALJ or the Council can decline to follow an LCD if the ALJ or Council provides a rationale.

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[6] NHIC LCD L11530. For purposes of processing Medicare claims for durable medical equipment, the country is divided into four quadrants and a contract is awarded for each of the quadrants. All four of the MACs that process claims for durable medical equipment ("DMACs"), are required to have identical LCDs. MPIM Ch. 13, §13.1.4. In October 2015, LCD L11530 was updated and given a new number, L33822. For the reader's ease, the original LCD number is used throughout this brief.

"Articles" are informal communications issued by MACs without consultation with the relevant medical community, typically addressing billing or coding issues, not coverage issues. Articles, by design, do not contain coverage determinations – only non-reasonable and necessary language can be communicated through Articles. Billing guidance explicitly is not a coverage policy. Under Medicare regulations, a MAC's Article is not entitled to any deference.[7] See also *Whitcomb v. Burwell*, 2015 WL 3397697 (E.D. Wis. May 26, 2015)[8]; *Finigan v. Burwell*, 2016 WL 2930905 (D. Mass May 19, 2016). NHIC issued Article A33614 stating it considered CGM "precautionary" and therefore not covered under the DME benefit.[9]

D. LCD Policy Challenges

Medicare regulations provide a mechanism for a Medicare beneficiary to file a challenge against an LCD. *See* 42 C.F.R. §426.400 et seq. The LCD challenge process is independent from the claims appeal process and is conducted by an ALJ who is a member of the Civil Remedies Division ("CRD") of the Departmental Appeals Board of the Department of Health and Human Services (the "Board"). *See* 42 C.F.R. §426.310. When a Medicare beneficiary files an LCD challenge, the relevant MAC is required to produce any information that the MAC considered when drafting the LCD including scientific articles, technology assessments, clinical guidelines and statements from clinical experts (the "LCD Record"). *See* 42 C.F.R. §426.418. The ALJ reviews the evidence submitted by the MAC and applying the reasonableness standard, determines whether the LCD Record is complete and adequate to support the validity of the LCD. *See* 42 C.F.R. §426.425(c). Either the Medicare beneficiary, the MAC or CMS may

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[7] See *In re The Rehab. Cntr.* M-2012-328 (Feb. 2012), 2012 WL 891183, AR 28-19. Unlike LCDs, which must be developed only after consultation with the relevant local medical community (MPIM Ch. 13, §13.7.1), articles do not require consultation to be published, are not subject to challenge, and are entitled to no deference. 42 C.F.R. §426.325(b)(9).

[8] AR 18-27.

[9] Article A33614 was updated in October 2015 and renumbered A52464. For the reader's ease, A33614 will be used throughout this document.

appeal an ALJ's determination regarding the validity of an LCD to the Board, but the Board's review is limited to the evidence considered during the LCD Record review. 42 C.F.R. §426.465(a),(b); 42 C.F.R. §§426.476(a)(3),(b).

E. Appeals of Medicare Claims Decisions

Congress has established a five-step process for a Medicare beneficiary to follow to obtain judicial review when she is dissatisfied with the Secretary's coverage determination of a claim for a device and supplies. See Complaint ¶¶ 43-60. The penultimate step is a hearing before an ALJ. A Medicare beneficiary may appeal an adverse ALJ decision to the Council, the final administrative appeal step. 42 C.F.R §405.1102. An NCD is binding on the Council. 42 C.F.R. §405.1060(a)(4). The Council typically does not conduct a hearing or allow oral argument, but has discretion to do so.[10] 42 C.F.R. §405.1124. The Council's decision is the Secretary's final agency decision for purposes of judicial review. 42 U.S.C. §§1395ff(b) and 405(g).

The Secretary's decisions are reviewed under the APA standard and must be based on substantial evidence in the record and must not otherwise be arbitrary, capricious, or an abuse of discretion or contrary to law. 42 C.F.R. §405.1136(f).

III. STATEMENT OF FACTS – CGM

A. Continuous Glucose Monitoring ("CGM")

Many individuals suffering from diabetes manage their disease by fingerstick glucose monitoring and subcutaneous injections of insulin. However, a segment of the population suffering from diabetes cannot control their diabetes through such methods, and they experience unpredictable glucose highs and lows (i.e., brittle diabetes), and suffer significant complications including stroke, loss of consciousness, retinopathy, nephropathy, neuropathy and death.

[10] The Council neither retained an expert nor conducted a hearing before rendering the Decision.

Individuals with hypoglycemic unawareness lack any physiologic warnings of such highs and lows, and may simply become confused or unconscious. Uncontrolled diabetes is the number one cause of kidney failure, non-traumatic lower limb amputations, and new cases of blindness among adults. AR 443, 450.

A CGM uses a cannula that is inserted into interstitial fluid and, using an algorithm, computes blood glucose levels every five minutes (approximately 288 times a day), including while the individual sleeps. AR at 769-770. A CGM indicates not only the glucose level at a specific time, but also trend information (how quickly the blood glucose is going up or down). The trend information allows a patient to take immediate action to control his or her glucose level, and is used by a clinician to devise a long term management plan for the patient's diabetes. Unlike blood glucose monitoring based on fingersticks, a CGM alerts a patient to unexpected glucose highs or lows. A CGM is the primary means by which people suffering from brittle diabetes and hypoglycemic unawareness control their glucose levels. CGM has been the subject of multiple peer-reviewed clinical studies, including large multi-center trials, which found improved clinical outcomes for people using a CGM to control their diabetes. AR 89-92, 97-211.

Numerous national and international professional organizations including the American Diabetes Association, the Endocrine Society, the American Association of Clinical Endocrinologists, the American Medical Association, and professional societies in other countries, recommend CGM for individuals suffering from Type 1 diabetes and include CGM in practice guidelines. Complaint ¶¶ 74, 75; AR at 17, 79-88, 93-96. An independent Federally-funded technology assessment found CGM reasonable and medically necessary for brittle diabetics. Complaint ¶ 78; AR 66-71.

In Summer 2016, in view of the precision of CGM in computing blood glucose levels, and the evolved medical practices, the FDA advisory panel recommended that the FDA remove the requirement that patients confirm CGM values before making insulin adjustments.[11] On December 21, 2016, the FDA modified the label on a standalone CGM such that confirmatory fingersticks are not required before an individual adjusts his or her insulin based on CGM readings.[12] Similarly, in view of the precision of current CGMs, in September 2016, the FDA approved a "closed loop" CGM/insulin pump system whereby the CGM directly informs the insulin pump when to administer insulin to control glucose levels.[13]

IV. STATEMENT OF FACTS – ADMINISTRATIVE PROCEEDINGS

Ms. Lewis has had Type 1 diabetes for over 30 years. As is common with individuals who have lived with Type 1 diabetes for an extended period, Ms. Lewis also suffers from hypoglycemia and hyperglycemic unawareness, i.e., she cannot sense when she is experiencing a glucose high or low. Consistent with the standard of care, Ms. Lewis' physician prescribed her a CGM to enable her to control her Type 1 diabetes.[14] For at least six years, her commercial insurance covered her CGM as a reasonable and medically necessary piece of durable medical equipment.[15] When Ms. Lewis became insured by Medicare, she submitted claims for her CGM sensors which were denied by NHIC.

Ms. Lewis appealed the denial through the Medicare administrative appeal process. An ALJ hearing was conducted on October 30, 2013. During the hearing, Ms. Lewis' physician, Dr. Richard Beaser, a national diabetes expert and faculty member of the Joslin Diabetes Center, testified that CGM was not precautionary, but was medically necessary and essential for Type 1

[11] http://www.medscape.com/viewarticle/866492.
[12] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm534056.htm.
[13] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm522974.htm.
[14] AR 72, 76.
[15] AR 762.

diabetics such as Ms. Lewis. Dr. Beaser testified that CGM prevents hypoglycemic and hyperglycemic events and premature death. AR 870-898.

The ALJ rendered an unfavorable decision finding that CGM is not covered by Medicare. Ms. Lewis appealed to the Council which affirmed the ALJ's denial of coverage of CGM although it modified the basis of denial. The Council found that "the contractor's LCD incorporates the provisions of its Policy Article" (AR 9), CGM is simply precautionary (akin to a spare oxygen tank), does not serve a medical purpose, and therefore is not covered under the DME Medicare benefit. AR 10. The Council declined to give weight to the American Medical Association Resolution that specifically supports CGM coverage for Medicare beneficiaries, a Wisconsin District Court case which held that the LCD does not incorporate the relevant Article and is not CMS program guidance entitled to deference, and an Order from the Civil Remedies Division discussed below. AR 11, fn 5.

Because a CGM requires monthly sensor supplies, during the pendency of the appeal of this first claim, Ms. Lewis filed claims for subsequent months of CGM supplies. Other ALJs rendered decisions for Ms. Lewis' claims finding that CGM and its supplies are a covered Medicare DME benefit and are reasonable and medically necessary for Ms. Lewis. See e.g., ALJ No. 1-3248004876 (issued Aug. 2015) (finding the Ms. Lewis' condition satisfied NCD 40.2 and LCD L11530 and CGM is reasonable and medically necessary for Ms. Lewis).

On December 26, 2014, while Ms. Lewis' appeal of her individual claim denial was pending at the Council level, Ms. Lewis also filed an LCD challenge of NHIC's statement that CGM is precautionary. See *In re: Local Coverage Determination Complaint: Glucose Monitors (L11530/L33822 and Local Coverage Articles A33614/A52464)*, DAB No. C-15-1021. On September 11, 2015, while Ms. Lewis' claim appeal was still pending at the Council level,

the CRD ALJ issued a ruling finding that the statement that CGM is precautionary was not supported by substantial evidence and finding that CGM meets the definition of DME. The ALJ found:

> The contractor and CMS have not produced any record in the form of peer-reviewed literature, medical opinions, or even any analysis from an individual with a medical background that supports a conclusion that a CGM is never reasonable and necessary irrespective of the beneficiary's condition. . . [T]here are not findings of fact, interpretations of law, and applications of fact to law by the contractor or CMS that are required to be given deference or that may be found reasonable.[16]

> On April 29, 2016, the CRD ALJ finally ruled:

> Based upon the evidence presented to me, CGM and at least some of its related accessories and supplies otherwise appear to meet the statutory definition of DME as interpreted by the Secretary: (1) most of its elements appear to be capable of withstanding repeated use; (2) they appear to have primarily and customarily a medical use for "brittle" diabetics in need of frequent glucose monitoring, which consists of monitoring a diabetic's glucose level for the purpose of detecting a sustainable glucose level and providing a warning if that level reaches a dangerously-low level that the beneficiary may be incapable of detecting without a CGM warning; (3) the monitor appears to have no utility absent Type 1 diabetes which is an illness; and (4) the CGM is designed for use in a home setting.

> The provision of the constructive LCD contained in LCD L11530/L33822 and LCA A33614/A52464 that states "[c]ontinuous glucose monitors (A9276-A9278) are considered precautionary and therefore not covered under the durable medical equipment benefit is not valid under the reasonableness standard."[17]

By this action, Ms. Lewis seeks judicial review of the September 25, 2015 Council decision M-14-1822 (the "Decision"). Below, we set forth the uncontradicted support in the AR showing that the CGM for Ms. Lewis is properly covered by Medicare under the DME benefit and request that the Court reverse the Secretary's finding and order coverage.

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[16] AR 44. The Council did not give weight to this CRD ruling finding that is was merely an interlocutory Order. AR 11, fn5. In April 2016, the September ruling finding the Article was not supported by substantial evidence, matured to a final ruling.

[17] See *In re: Local Coverage Determination Complaint: Glucose Monitors (L11530/L33822 and Local Coverage Articles A33614/A52464)*, DAB No. C-15-1021 (April 26, 2016) (the "CRD Decision") at 20, 22.

V. STANDARD OF REVIEW

Under the Medicare statute, 42 C.F.R. § 1395ff(b), the final agency decisions included in this action are subject to judicial review under the applicable provisions of the APA.[18] The measure of deference owed to an agency decision "has been understood to vary with circumstances, and courts have looked to the degree of the agency's care, its consistency, formality and relative expertness, and the persuasiveness of the agency's position."[19] Council decisions are evaluated under the four factor *Skidmore* standard. *Tangney v. Burwell*, 186 F.Supp.3d 45 (D. Mass. 2016). Under a *Skidmore* analysis, among other factors, the court considers (1) the agency's consistency; (2) the thoroughness the Decision including whether the agency consulted appropriate sources and adequately substantiated its conclusion.

Agency interpretation of statutory Council decisions are only entitled to deference where Congress has not clearly spoken to the meaning of a statutory term and where the nature and circumstances of the interpretation confer dispositive weight upon that interpretation. *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.,* 467 U.S. 837, 865 n9 (1984). Under the *Chevron* standard, the Court must determine whether the Secretary's actions are arbitrary and capricious, an abuse of discretion, not based on substantial evidence, or otherwise not in accordance with law. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 414-17 (1971). If so, the Court must set it aside.

In *Motor Vehicle Manufacturers Ass'n of the United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), the Supreme Court described the "arbitrary and capricious" standard as follows:

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[18] 42 U.S.C. §405(g), See also *St. Francis Hospital v. Sebelius*, 09 CV 1528, NYLJ 1202666932167, at *1 (EDNY, Decided July 23, 2014) and *Pavano v. Shalala*, 95 F.3d 147, 150 (2d Cir. 1996).

[19] United States v. Mead Coprt., 533 U.S. 218, 228 (2001)(Citing Skidmore v. Swift & Co., 323 U.S. 134, 139-140(1944) (footnotes omitted).

> Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Id. at 63. Similarly, the "substantial evidence" standard requires an in-depth review of the facts relied upon by the agency in its decision:

> A 'substantial evidence' standard, however, does not permit a court to uphold the Secretary's decision by referring only to those parts of the record which support the [Secretary]. A reviewing court must view the entire record and take account of evidence in the record which detracts from the evidence relied on by the [Secretary].

Tieniber v. Heckler, 720 F.2d 1251, 1253 (11th Cir. 1983); *accord Brown v. Bowen*, 794 F.2d 703, 705 (D.C. Cir. 1986) ("Our review in substantial-evidence cases calls for careful scrutiny of the entire record."). A reviewing court may uphold agency action only on the basis articulated by the agency in its decision, not on *post-hoc* rationalization offered by the agency or its counsel. *See Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 631 n.31 (1980); *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 169 (1962); *Biloxi Regional Medical Center v. Bowen*, 835 F.2d 345, 348 n.12 (D.C. Cir. 1987).

In *Malcomb v. Island Creek Coal Co.*, 15 F.3d 364 (4th Cir. 1994), the court stated:

> When the agency's varying interpretations of a regulation have not been the result of the agency making considered changes in its policy, but rather of the agency simply acting inconsistently without explanation, however, 'the case for judicial deference is less compelling.' ***Moreover, if the agency's record of unexplained inconsistent interpretation is particularly egregious, the interpretation that the agency applied in the case before the court is entitled to no deference.***

15 F.3d at 369 (emphasis added; citations omitted).

VI. ARGUMENT

The Secretary makes fundamental errors in her Decision and is not entitled to deference under a *Skidmore* standard.[20] First, to the extent the Secretary's Decision asserts CGM does not meet the definition of DME because it does not perform a medical purpose, the Secretary's decision is not supported by substantial evidence and is contrary to the overwhelming evidence in the administrative record and public knowledge regarding CGM. Second, the Secretary improperly states the Article is incorporated in the LCD and accords it deference. Thus, the Decision is contrary to law. Third, even if the Article had been an LCD and entitled to deference (which it is not), based on (1) the determination that the Article is invalid under the reasonableness standard; (2) the overwhelming evidence that the consensus of the experts and physicians agree CGM is primarily a medical device that is reasonable and medically necessary for individuals suffering from Type 1 diabetes; (3) the Article's failure to show consideration of the numerous national and international consensus statements, peer-reviewed articles and technology assessments; and (4) Ms. Lewis' unrefuted medical need for CGM, coverage is warranted despite the unsupported and discredited statement in the Article. The Decision is contrary to her binding NCDs and the relevant LCD. Finally, the Secretary has paid for CGM and its supplies for medically indistinguishable beneficiaries and has paid other claims for Ms. Lewis. Thus, the Decision is arbitrary and capricious.

Despite the Secretary's NCDs and numerous public statements exhorting individuals with diabetes to control their diabetes, the Secretary denied this claim for a device that is necessary for this Medicare beneficiary to control her diabetes and prevent complications therefrom. As

[20] Because the Secretary's failure to meet the *Chevron* standard of review necessarily shows she fails the *Skidmore* standard of review, the *Chevron* standard is referenced as the lack of evidence supporting the Decision.

explained below, the Secretary's reasons for denying the claims lack a basis in law and fact and must be reversed by this Court.

A. CGM is DME

A CGM is eligible for coverage under the Medicare DME benefit.

1. CGM is Primarily a Medical Device

CMS has a long history of construing the DME benefit broadly as Congress intended. *CRD Decision* at 18 (citing HCFA Ruling 96-1 at 6 and DAB No. 1999 at 3 (2005)). The gravamen of the Secretary's denial is that CGM does not meet the definition of DME because it does not serve primarily a medical purpose and is simply an added precaution advising a beneficiary of the need to conduct a fingerstick test. Such an assertion reflects a fundamental misunderstanding regarding the nature of CGM and its role in the management of diabetes.

First, CMS has observed that "in most instances, no development will be needed to determine whether a specific item of equipment is medical in nature" and that when such "development" is needed, it will be based on consultation with specialists and medical societies. See MBPM, Chapt. 15, §110.1(B)1. The FDA, AHRQ, the National Institutes of Health, the relevant professional medical societies,[21] experts in the care of diabetes (including Ms. Lewis' treating physician) and commercial insurance payers deem CGM to be a medical device. No medical expert has opined otherwise.

The Secretary's Decision, and her Answer,[22] indicate that contrary to the requirement, the Secretary did not consult with or consider the opinions of specialists or medical societies.[23] In

[21] See Complaint ¶¶ 74, 75, 77, 78; AR 66-71, 78-96, 139-151.
[22] The Secretary asserted she lacked sufficient information or knowledge regarding the various cited consensus statements of national and professional organizations recommending CGM, the federally funded technology assessment, and the widespread acceptance of CGM. See Secretary's Answer at 7.
[23] MBPM, Chapt. 15, §110.1(B)1.

addition to expert opinion, coverage of CGM is supported by the peer-reviewed literature.[24] The Secretary's Decision reflects neither awareness nor consideration of the relevant peer-reviewed literature, assessments or medical standards.[25]

Second, as conceded by the Secretary, "precautionary" is not a statutorily defined term. However, the exemplar of precautionary equipment, a spare preset oxygen tank, underscores the difference between such a "precautionary device" and a CGM. Precautionary devices are backups. A CGM is used for the continuous medical management of diabetes and is the primary method of glucose monitoring for individuals with brittle diabetes and hypoglycemic unawareness.[26] No Medicare beneficiary can test his or her glucose levels with the frequency of a CGM (288 times a day) and certainly none can test while they are sleeping – the time when most individuals suffering from Type 1 diabetes experience fatal lows. Fingersticks testing cannot identify the sudden and unpredictable drops in Ms. Lewis' blood glucose levels.

The Council asserted that a CGM serves a duplicative function and does not substitute for the existing means of controlling insulin usage. AR 10 and 11. The Council misconstrues the nature of a CGM device which not only provides the "snapshot" of a blood glucose level (like a fingerstick), but provides trend information about whether the glucose level is rising or falling and how fast. Fingersticks do not provide such information. Clinicians use the trend data to devise long-term diabetes management plans. Patients use trend data in real time to determine how quickly they must adjust their insulin levels.[27]

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[24] AR 72-76, 97-211, 605-612. See MPIM §13.7.1 indicating peer-reviewed literature should be considered in making coverage decisions.
[25] The Council stated it would not give weight to the American Medical Association's consensus statement affirming CGM as the standard of care for diabetics stating such a consensus statement is not binding. Although the AMA resolution is not binding, it reflects the consensus of the medical community, a primary factor in making coverage determinations. See MPIM, Ch. 13, §13.7.1.
[26] AR 881, 901.
[27] AR 872, 874-881.

2. Confirmatory Testing Does Not Undermine DME Status

A possible confirmatory fingerstick test does not deprive a CGM of its "primary medical" nature. Medicare pays for both presumptive testing and confirmatory testing in many circumstances including testing for drugs of abuse.[28] Numerous laboratory tests are performed and covered by Medicare on a "reflex" basis, i.e., if the value of the first test exceeds a designated threshold, the second test is performed. Thus, a possible confirmatory test does not impair the primarily medical nature of the test. The Secretary cites no authority for her novel statement that a device loses its medical nature if either a confirmatory test is performed or another medical device is used.[29]

Regardless of the foregoing, because CGM so closely corresponds to the blood glucose level reading provided by fingerstick testing, in 2016, the FDA removed the requirement that CGM readings be confirmed by a fingerstick before making an insulin adjustment. Further, in September 2016, the FDA approved a "closed loop system" wherein the CGM communicates directly with an insulin pump to regulate insulin without an intermediary confirmatory fingerstick. Thus, to the extent the Secretary's Decision deems CGM to not be DME because its readings may be confirmed with a fingerstick test, that rationale has been obviated by the FDA's rulings with respect to CGM - rulings which recognize a CGM can be the primary or sole means by which diabetics control their blood glucose levels.

B. The Article is Not an LCD and is Not Entitled to Deference

Throughout her Decision, the Secretary improperly equates an Article with an LCD. As noted above, pursuant to statute and Medicare regulations, an Article explicitly is not a coverage

[28] http://www.palmettogba.com/palmetto/providers.nsf/vMasterDID/A59PK51218?OpenDocument.
[29] The Secretary's logic would make all monitoring devices non-medical or precautionary in nature. For example, a heart monitor would be non-medical because a different medical device, a defibrillator, is required to restart a stopped heart. This Court in *Finigan* noted such logic was "head-scratching" at best. *Finigan* at fn. 6.

policy. Although in *Whitcomb*, the District Court explicitly ruled that an Article was not entitled to deference and that the Article was not incorporated into the LCD, the Council did not consider that ruling asserting that "District Court decisions are not binding or precedential; moreover the cited decision considered the provisions of a different LCD and policy article." AR 11, fn 5. The Secretary's assertion that the *Whitcomb* case involved a different article is disingenuous – all DMACs are required to have substantively identical LCDs and articles.[30] Further, contrary to the Secretary's assertion, as the *Whitcomb* court found, the LCD does not incorporate the Article by reference, but simply identifies the Article as a "Related Document." AR 24. The rationale of *Whitcomb* has been adopted by this Court. See *Finigan*. Even if the LCD had incorporated the Article by reference, the Article would not be entitled to the same deference as an LCD, because Articles are not based on peer-reviewed literature, consultation with the relevant medical community or with consideration of standards within the relevant medical community. MPIM Ch. 13, §13.7.1. Thus, to the extent the Secretary's Decision is based on her improper elevation of an Article to LCD status, it must be set aside as contrary to law.

Finally, even if Article A33614 enjoyed LCD status, or even the status of program guidance, which it does not, the Council should not have applied the Article because (1) the CRD found the Article invalid under the reasonableness standard; (2) based on the overwhelming evidence that CGM is recognized as the standard of care and the primary means by which individuals suffering from Type 1 diabetes control their disease; (3) the Article's failure to show consideration of the peer-reviewed literature, consensus of experts, and acceptance by the relevant community; and (4) as is discussed more fully below, Ms. Lewis' clear need for CGM to avoid serious complications from her diabetes. Coverage determinations that are contrary to the standard of care must be supported by convincing evidence. MPIM, Ch. 13, §13.8. The

[30] MPIM Ch. 13, §13.1.4.

Secretary cites no evidence in support of the assertion that CGM is precautionary, and the CRD explicitly found the assertion that CGM is precautionary is invalid under the reasonableness standard, i.e., insufficient evidence supports such a determination.

C. Medicare Coverage is Appropriate Based on Ms. Lewis' Medical Condition

Ms. Lewis has a clear medical need for CGM. Substantial evidence does not exist in the administrative record to refute the documentary and testimonial medical evidence supporting Ms. Lewis' medical need for CGM. In fact, no evidence supports the denial. The Secretary did not discuss Ms. Lewis' medical condition, her inability to detect glucose lows without the CGM, the significant complications that can devolve from hypoglycemic unawareness, and the significant cost to Medicare when Ms. Lewis is unable to control her diabetes. Not only did the Secretary not discuss the foregoing, but she did not discuss a reason for rejecting the opinion of Ms. Lewis' physicians and providers which include experts in the treatment of diabetes.[31]

In CMS Ruling 93-1, issued on May 18, 1993, the Secretary addressed the applicability of the "treating physician's rule" in Medicare cases. The CMS Ruling states, in pertinent part, as follows: "The final determination by the medical review entity should not be based solely on the physician's opinion, but should reflect its evaluation of all documentation contained in the medical record." Accordingly, where the treating physician's opinion is supported by the documentation in the medical record, it may not be rejected by the Secretary for Medicare purposes.

Many courts have recognized that the treating physician rule should apply with equal force in Medicare cases. As one court explained,

> It is a well-settled rule in Social Security disability cases that the expert medical opinion of a patient's treating physician is to be accorded deference by the

[31] AR 72-77, 605-612, 871-891.

> Secretary and is binding unless contradicted by substantial evidence. This rule may well apply with even greater force in the context of Medicare reimbursement. The legislative history of the Medicare statute makes clear the essential role of the attending physician in the statutory scheme: "The physician is to be the key figure in determining utilization of health services."

Gartmann v. Secretary of U.S. Dept. of Health and Human Services, 633 F. Supp, 671, 680-681 (E.D. N.Y. 1986), quoting, 1965 U.S. Code Cong. And Ad. News, 1943, 1986. This is especially compelling where, as in the cases herein, there is "no direct conflicting evidence." *Kuebler v. Secretary of U.S. Dept. of Health & Human Services*, 579 F. Supp. 1436 (D.C. N.Y. 1984).

The treating practitioners' opinions are supported by the medical record, there is no evidence to the contrary in the AR, and the Secretary has failed to provide a "reasoned basis" for refusing to accept their opinions. See *Heart 4 Heart v. Sebelius*, 2014 WL 3028684 at 8-9 (C.D. Ill) (citing *Clifford v. Apfel*, 227 F.3d 863, 869 (7th Cir. 2000). Although the ALJ and the Council could have retained an independent expert to opine on the medical necessity of CGM, neither retained such an expert. Accordingly, the Secretary has no legal or factual basis to deny coverage on the grounds that it is not medically reasonable and necessary for Ms. Lewis.

D. The Decision is Arbitrary and Capricious Because it is Inconsistent with NCD 280.1, NCD 40.2, the LCD, and the Secretary's Other Decisions

The Secretary's Decision is arbitrary and capricious because it conflicts with the NCDs 280.1 and 40.2. CGM measures blood glucose levels, albeit through interstitial fluid using an algorithm. NCD 280.1 explicitly deems glucose monitors to be DME provided the beneficiary (not a device) meets the coverage criteria of NCD 40.2. Ms. Lewis satisfies the coverage criteria of NCD 40.2. Although NCD 40.2 focuses on fingerstick glucose meters, it does not exclude CGM and does not limit the broader coverage afforded by NCD 280.1 which deems blood glucose monitors to be DME.

Similarly, LCD L33822 indicates the coverage criteria for glucose monitors and recognizes the need for diabetics to control their diabetes through frequent testing. The billing codes for the CGM and its supplies are listed in the LCD and are not excluded from coverage. Again, Ms. Lewis satisfies the LCD coverage criteria.

Finally, not only has the Secretary found CGM to be a covered Medicare benefit for other Medicare beneficiaries whose medical condition is indistinguishable from Ms. Lewis' condition,[32] but when adjudicating other CGM claims for Ms. Lewis, she has deemed CGM to be covered. The Secretary has rendered favorable CGM decisions before and after she rendered this Decision. Thus, the Secretary's Decision is arbitrary and capricious and must be reversed. In *Independent Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1246, 1260 (D.C. Cir. 1996), the court stated:

> The treatment of cases A and B, where the two cases are functionally indistinguishable, must be consistent. That is the very meaning of the arbitrary and capricious standard.

VII. CONCLUSION

The Secretary's Decision is contrary to law and facts. CGM is the primary medical device by which individuals with brittle Type 1 diabetes and hypoglycemic unawareness control their diabetes. CGM is recognized as the standard of care by every relevant national medical society, Federal agencies and commercial payers. The Secretary's Decision is not entitled to deference because it misapplies the Article and ignores District Court decisions, the Civil Remedies Division ruling invalidating the Article and the standard of care. Coverage is consistent with NCD 40.2, NCD 280.1, and LCD L33822. The Decision is inconsistent with other final decisions. For the foregoing reasons, this Court should grant Plaintiff Lewis' Motion for Summary Judgment.

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[32] At least 20 other Medicare beneficiaries suffering from Type 1 diabetes have received final favorable ALJ determinations that CGM is covered under the Medicare DME benefit and is reasonable and medically necessary for them.

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Respectfully submitted,
CAROL LEWIS, By her attorneys,
/s/ Laurie J. Bejoian

LAURIE J. BEJOIAN BBO No. 545312
325B Great Road
Littleton, MA 01460
978-486-9145
ljblaw.ljbejoian@gmail.com

OF COUNSEL
DEBRA M. PARRISH
PARRISH LAW OFFICES
788 Washington Road
Pittsburgh, PA 15228
412-561-6250
debbie@dparrishlaw.com